K121447
Page 1 of 6

510(k) SUMMARY
iSchemaView, Inc.'s *RAPID*

Applicant's name: iSchemaView, Inc.
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Date Prepared: September 13, 2013

Name of Device: *RAPID*

Common or Usual Name: PACS – Picture Archiving Communications System

Classification: **Product Code:** LLZ
Regulation No: 21 C.F.R. §892.2050
Class: II
Classification Panel: Radiology Devices

Predicate Devices

OLEA MEDICAL's Olea Sphere (K120196)

Device Description

RAPID is a software package that provides for the visualization and study of changes of tissue perfusion and diffusion in digital images captured by CT (Computed Tomography) and MRI (Magnetic Image Resonance). *RAPID* can be installed on a customer PC or it can be accessed online as virtual system. It provides viewing, quantification, analysis and reporting capabilities.

RAPID works with the following types of (DICOM compliant) medical image data:

- CT (Computed Tomography)
- MRI (Magnetic Image Resonance)

RAPID acquires (DICOM compliant) medical image data from the following sources:

- DICOM file
- DICOM CD-R
- Network using DICOM protocol

RAPID provides tools for performing the following types of analysis:

- volumetry of threshold maps
- time intensity plots for dynamic time courses
- measurement of mismatch between labeled volumes on co-registered image volumes

RAPID is a software-only device consisting of one or more *RAPID* Servers (dedicated or virtual and an iSchemaView Server). The *RAPID* Server is an image processing engine that connects to a hospital LAN, inside the Hospital Firewall. It can be a dedicated RAPID Server or a vmRAPID appliance, which is a virtualized *RAPID* Server that runs on a dedicated hospital server. Where available, the *RAPID* Server is placed logically in the demilitarized zone (DMZ) of the hospital's network to facilitate bidirectional secure connection between the (local) *RAPID* Server and the centralized iSchemaView Server.

The *RAPID* Server is configured to connect to applicable DICOM devices (PACS, Imaging Modalities, Research Workstations) via the hospital LAN and to receive diffusion and perfusion (DICOM) data directly and automatically from imaging modalities as they become available. It processes acquired data and delivers postprocessed images directly back to imaging modalities, local PACS and/or workstations, again using DICOM communication. It also transmits data to the iSchemaView Server for storage, retrieval and viewing.

The iSchemaView Server is a dedicated server that provides a central repository for *RAPID* data. All iSchemaView Server data is stored on encrypted hard disks. It also provides a user interface for accessing *RAPID* data. It connects to a firewalled Data Center Network and has its own firewall for additional data security. The iSchemaView Server connects to one or more *RAPID* Servers via WAN. Available types of connection include VPN (Virtual Private Network - RFC2401 and RFC4301 Standards) Tunnel and SSH (Secure Shell).

Intended Use / Indications for Use

iSchemaView's *RAPID* is an image processing software package to be used by trained professionals, including but not limited to physicians and medical technicians. The software runs on a standard "off-the-shelf" computer or a virtual platform, such as VMware, and can be used to perform image viewing, processing and analysis of brain images. Data and images are acquired through DICOM compliant imaging devices.

iSchemaView's *RAPID* provides both viewing and analysis capabilities for functional and dynamic imaging datasets acquired with CT Perfusion and MRI including a Diffusion Weighted MRI (DWI) Module and a Dynamic Analysis Module (dynamic contrast enhanced imaging data for MRI and CT).

The DWI Module is used to visualize local water diffusion properties from the analysis of diffusion-weighted MRI data.

The Dynamic Analysis Module is used for visualization and analysis of dynamic imaging data, showing properties of changes in contrast over time. This functionality includes calculation of parameters related to tissue flow (perfusion) and tissue blood volume.

Technological Characteristics

RAPID performs the following functions:

- processes DICOM images from multiple sources to provide visualization of changes of tissue perfusion and diffusion
- receives DICOM images from external DICOM image providers (modalities (CT/MRI Scanners), PACS and Workstations) and sends DICOM images to external image consumers
- processes requests, statuses and results, and references therein, which are stored in a queryable database
- processing status is available through a web browser using HTTP, HTML and PHP.
- can send summary results to the user over email. For this, *RAPID* generally connects to the infrastructure of the medical partner (e.g., the hospital). In particular, *RAPID* uses a SMTP protocol with security extensions to provide secure emailing.

RAPID is available in the following configurations:

- Standard *RAPID*, which is installed directly on a customer's Linux-based PC and integrated with medical image processing software such as commercial PACS.
- Virtual *RAPID*, wherein the user accesses *RAPID* online and uses it to process DICOM images otherwise available on his/her computer.

RAPID is a DICOM-compliant PACS software that provides comprehensive functionality to transfer, process, and display diffusion-weighted MRI (DWI) and dynamically acquired CT and MR imaging data (following the administration of a bolus of contrast media). *RAPID* runs on standard "off-the-shelf" computer and networking hardware. *RAPID* is entirely independent from CT, MRI, or PACS platforms. It supports secure VPN (Virtual Private Network) networking or encapsulated Secure Shell (SSH), and seamlessly integrates into an existing radiological data network.

The primary users of *RAPID* PACS software are medical imaging professionals who analyze diffusion MRI and/or dynamic CT or MRI images. The images generated by *RAPID* provide additional diagnostic information, which is derived from the temporal/diffusion features of the native CT or MRI images.

Performance Data

RAPID complies with DICOM (Digital Imaging and Communications in Medicine) - Developed by the American College of Radiology and the National Electrical Manufacturers Association. NEMA PS 3.1 - 3.20 (2011).

Additionally, iSchemaView conducted extensive performance validation testing and software verification and validation testing of the *RAPID* system. This performance validation testing demonstrated that the *RAPID* system provides accurate representation of key diffusion and perfusion processing parameters under a range of clinically relevant parameters and perturbations associated with the intended use of the software. Software validation and verification testing demonstrated that the *RAPID* system met all design requirements and specifications.

Substantial Equivalence

RAPID is as safe and effective as the Olea Sphere. *RAPID* has the same intended use and similar indications, technological characteristics and principles of operation as its predicate device. The minor technological differences between the *RAPID* and its predicate raise no new issues of safety or effectiveness as demonstrated by the testing conducted with *RAPID* that confirms that the software reliably processes CT diffusion and MRI diffusion and perfusion medical images. Thus, the *RAPID* software is substantially equivalent.

Substantial Equivalence

Parameter	*RAPID*	**Olea Sphere (K120196)**
Product Code	LLZ	LLZ
Regulation	21 CFR §892.2050	21 CFR §892.2050
Intended Use/ Indications for Use	iSchemaView's RAPID is an image processing software package to be used by trained professionals, including but not limited to physicians and medical technicians. The software runs on a standard "off-the-shelf" computer or a virtual platform, such as VMware, and can be used to perform image viewing, processing and analysis of brain images. Data and images are acquired through DICOM compliant imaging devices. The iSchemaView RAPID provides both viewing and analysis capabilities for functional and dynamic imaging datasets acquired with CT Perfusion and MRI including a Diffusion Weighted MRI (DWI) Module and a Dynamic Analysis Module (dynamic contrast-enhanced imaging data for MRI and CT). The DWI Module is used to visualize local water diffusion properties from the analysis of diffusion-weighted MRI data. The Dynamic Analysis Module is used for visualization and analysis of dynamic imaging data, showing properties of changes in contrast over time. This functionality includes calculation of parameters related to tissue flow (perfusion) and tissue blood volume.	Olea Sphere is an image processing software package to be used by trained professionals including but not limited to physicians and medical technicians. The software runs on a standard "off-the-shelf" workstation and can be used to perform image viewing, processing and analysis of medical images. Data and images are acquired through DICOM compliant imaging devices and modalities. Olea Sphere provides both viewing and analysis capabilities of functional and dynamic imaging datasets acquired with MRI or other relevant modalities, including a Diffusion Weighted MRI (DWI) / Fiber Tracking Module and a Dynamic Analysis Module (dynamic contrast enhanced imaging data for MRI and CT). The *DWI* Module is used to visualize local water diffusion properties from the analysis of diffusion-weighted MRI data. The Fiber Tracking feature utilizes the directional dependency of the diffusion to display the white matter Structure in the brain or more generally the central nervous system. The Dynamic Analysis Module is used for visualization and analysis of dynamic imaging data, showing properties of changes in contrast over time where such techniques are useful or necessary. This functionality is referred to as: Perfusion Module - the calculation of parameters related to tissue flow (perfusion) and tissue blood volume. Permeability Module - the calculation of parameters related to leakage of injected contrast material from intravascular to extracellular space.
PACS Functionality		
Basic PACS Functions	View, process and analyze medical images. Performs standard PACS functions with respect to querying and listing.	Same
Computer Platform	Standard "off-the-shelf" PC workstation[1]	Same

[1] Note: *RAPID* also may be used with a virtual platform such as VMware.

DICOM Compliance	Yes	Yes
Funcional Overview	*RAPID* is a software package that provides for the visualization and study of changes of tissue perfusion and diffusion in digital images captured by CT and MRI. *RAPID* provides viewing and quantification.	Same
Data Acquisition	Acquires medical image data from DICOM compliant imaging devices and modalities	Same
Data/Image Types	Computed Tomography (CT) Magnetic Image Resonance (MRI)	Same
Acquisition and Modalities Features		
MRI	Diffusion Weighted Image (DWI) Perfusion Weighted Image (PWI)	Yes Yes
CT	CT Perfusion (CTP)	Yes
Computed Parameter Maps		
Diffusion MRI	Isotropic DWI (isoDWI)	Yes
	Exponential apparent diffusion coefficient (eADC)	Yes
	ADC	Yes
	Trace of diffusion tensor (Trace)	Yes
	Fractional Anisotropy (FA) and color FA	Yes
	Eigenvector	Yes
	Eigenvalue	Yes
Perfusion MRI and Perfusion CT	Cerebral blood flow (CBF)	Yes
	Cerebral blood volume (CBV)	Yes
	Mean transit time (MTT)	Yes
	Tissue residue function time to peak (Tmax)	Yes
Measurements/Tools		
MRI and CT Tools	Arterial input function (AIF)/Venous output function (VOF)	Yes
	Time-course	Yes
	Brain mask	Yes
	Region of interest (ROI) and Volumetry	Yes
	Volumetric comparison between 2 ROIs	Yes
	Motion correction	Yes
	Export perfusion and diffusion files to PACS and DICOM file systems	Yes
	Acquire, transmit, process, and store medical images	Yes

K121440
Page 6 of 6
0137

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

October 4, 2013

iSchemaView, Inc.
% John J. Smith, M.D., J.D.
Partner
Hogan Lovells US LLP
Columbia Square
555 Thirteenth Street, NW
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Re: K121447
Trade/Device Name: *RAPID*
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: September 16, 2013
Received: September 16, 2013

Dear Dr. Smith:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Janine M. Morris
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K121447

Device Name: iSchemaView's *RAPID*

Indications for Use:

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Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)

(Division Sign-Off)
Division of Radiological Health
Office of *In Vitro* Diagnostics and Radiological Health

510(k) ___K121447_____